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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/722,544	11/28/2000	Hong Chen	07334-362001 / MPI98-033P	6903

7590

07/19/2002

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EXAMINER

WILDER, CYNTHIA B

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 07/19/2002

15

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/722,544

Applicant(s)

CHEN ET AL

Examiner

Cynthia Wilder

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11/28/00.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 19-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 19-31 is/are rejected.
- 7) ☒ Claim(s) 21 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 November 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *Detailed Action*.

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### **DETAILED ACTION**

1. Applicant's preliminary amendment filed in Paper No. 12 is acknowledged. Claim 1 has been amended. Claims 2-18 have been deleted. Claims 19-31 have been added. Claims 1 and 19-31 are pending. An action on the merit appears below for the pending claims.

#### ***Objections***

2. The specification and claim 21 is objected to because of the following informalities:

- (a) The specification is objected to at pages 10-12, 40, 44, 45 and 54 for the "*HKNG* gene" because the terminology is not consistent throughout the specification. Likewise the term makes reference to the *HKNG1* gene which is supported by the specification as originally filed. It is suggested changing "*HKNG* gene" to "*HKNG1* gene" as supported by the specification as originally filed.
- (b) The specification is objected to at pages 13, 52-54 for "SEQ ID Nos." because the designation for the sequence identifier is improper. It is suggested changing "SEQ ID Nos." to "SEQ ID NOS:"
- (c) In claim 21, the spacing between the "w" and "herein" should be deleted such that the word reads "wherein".

#### ***Claim Rejections - 35 USC § 112 First paragraph (Deposit Requirement)***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 29 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it most nearly connected, to make and/or used the invention. The specification lacks deposit information for the deposit of the clone contained in ATCC, Accession Number 98351 as disclosed in the claim. While the specification provides extensive information for one of skill in the art to produce a cDNA sequence, reproduction of the identical cDNA insert of the clone as claimed is an extremely unpredictable event.

It does not appear that the clone contained in ATCC Accession Number 98351 is known and readily available or can be reproducibly made or isolated from nature without undue experimentation, and because claim 29 specifically requires a clone contained in the Accession Number 98351, a suitable deposit of the clone may be made to satisfy enablement for patent purposes. Applicant's disclosure in the specification is not considered sufficient assurance that all of the conditions of 37 CFR 1.801-1.809 have been met. If a deposit is made under the terms of the Budapest Treaty, than an affidavit or declaration by Applicant(s), or a statement by an attorney of record over his or her signature and registration number, stating that the instant invention will be irrevocably and without restriction released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. If a deposit has not been made under the Budapest Treaty, than in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809 and MPEP

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2402-2411.05, Applicant may provide assurance of compliance by affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that:

- (a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public for the enforceable life of the patent;
- (d) a test of the viability of the biological material at the time of the deposit (see 37 CFR 1.807); and
- (3) the deposit will be replaced if it should ever become inviable.

This requirement if necessary when a deposit is made under the provisions of the Budapest Treaty as the Treaty leaves these specific matters to the discretion of each member State. Amendment of the specification to recite the date of the deposit and the complete name and address of the depository is required along with a statement verifying whether or not the deposit was made under the Budapest Treaty.

***Claim Rejections - 35 USC § 112 second paragraph (indefiniteness)***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his invention.

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6. Claim 1, 19-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

(a) Claims 1, 19-31 are indefinite at "capable of" in step (a) of claim 1 and 19 because it cannot be determined whether "capable of" is a property of the labeled antibody or a separate step. Additionally the language is a non-specific activity (see *Ex parte Erlich*, 3 USPQ2d 1011 at 6). It is suggested amending the claim to recite active and positive method steps by changing "capable of identifying" in step (a) to "which identifies".

(b) Claim 1, 19-31 are indefinite at *HKNGI*", "*HKNG*" and "*HGNG*" because abbreviations often have more than one meaning in the art. It is suggested inserting the full name of the abbreviation in the claims as supported by the specification as originally filed.

(c) Claims 1, 19-31 lacks proper antecedent basis for " the *HKNG* gene" because the prior steps do not recite "a *HKNG* gene" but recites " a *HKNGI* gene". It is suggested amending the claims such that the claims language agree.

(d) Claims 1-19-31 lack proper antecedent basis for "the *HGNG* gene" because the prior steps do not recite "a *HGNG* gene" but recites "a *HKNGI* gene". it is suggested amending the claims such that the claims language agree.

(e) Claim 21 is indefinite at "Elisa" because the term is an abbreviation for "enzyme-linked immuno-sorbent assay" and should be capitalized. Likewise abbreviations often have more than one

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meaning in the art. Therefore, it is suggested inserting the full name of the abbreviation into the claim.

### ***Double Patenting***

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1, 19-31 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1-9 of co-pending Application

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No. 09/236, 134. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims only slightly differ in scope.

The claims of the instant invention differs from the claims of the co-pending application in that they are drawn to an immunoassay for detecting the HKNG1 gene product whereas the claims 1-9 of co-pending Application 09/236,134 are drawn to a hybridization method and protein assay method for identifying an individual at risk of developing a bipolar affective disorder or schizophrenia. Both the claims of the instant invention and co-pending application 09/236,134 teach wherein a mutation in the HKNG1 gene or the HKNG1 gene product comprise a substitution of a lysine for a glutamic acid at amino acid residue 202 of SEQ ID NO: 2 or a substitution of a lysine for a glutamic acid at amino acid residue 184 of SEQ ID NO: 4. Accordingly, the the slight variation in scope between the claims of the instant invention and co-pending application '134 are not patentably distinct.

This is a provisional obviousness-type double patenting rejection.

***Closest Prior Art.***

9. The closest prior art, Shizimu, A (Genbank ACC, No. D63813) disclose an amino acid sequence of a potential rod photoreceptor protein found in the human retina that is slightly similar to, but not identical to the amino acid sequence of SEQ ID NO: 2. Adams et al. (Nature 377 (6547 suppl), pages 3-174, October 1995) disclosed the analysis of 174,472 partial complementary



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DNA sequences (expressed sequence tags (ESTs) wherein one of the sequence comprised a portion of the sequence of SEQ ID NO:2.

No prior art was found teaching a method of detecting an HKNG1 gene product associated with bipolar affective disorder and/or schizophrenia. No prior art was found teaching an amino acid sequence comprising the sequence of SEQ ID NO: 2 with a substitution of a lysine for a glutamic acid at residue 202 of SEQ ID NO: 2 or an amino acid sequence comprising the sequence of SEQ ID NO: 4 having a substitution of a lysine for glutamic acid at amino acid residue 184 of SEQ ID NO: 4.

### ***Conclusion***

10. No claims are allowed. However the claims are free of the prior art.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cynthia Wilder whose telephone number is (703) 305-1680. The examiner can normally be reached on Monday through Thursday from 7:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached at (703) 308-1119. The official fax phone number for the Group is (703) 308-4242. The unofficial fax number is (703) 308-8724.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group's Patent Analyst, Monica Graves at (703) 305-3002 or Group's receptionist at (703) 308-0196.

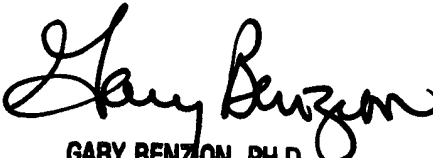
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Cynthia B. Wilder, Ph.D.

July 8, 2002

  
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